10/584105

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	18 APR 2005
Applicant's or agent's file reference 66090-16	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US04/43253	22 December 2004 (22.12.2004)	22 December 2003 (22.12.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61L 02/00; A01N 25/00, 25/24 and US Cl.: 422/28; 424/405, 407, 665; 106/15.05

Applicant

INSTITUTE FOR ENVIRONMENTAL HEALTH, INC.

1. This opinion contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis(b)* that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Sun (John) Kim Telephone No. (703) 308-0661

Form PCT/ISA/237 (cover sheet) (January 2004)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/43253

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ in written format

      ☐ in computer readable form

   c. time of filing/furnishing

      ☐ contained in international application as filed.

      ☐ filed together with the international application in computer readable form.

      ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/43253

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 11-21	YES
	Claims 1-10, 22-30	NO
Inventive step (IS)	Claims None	YES
	Claims 1-30	NO
Industrial applicability (IA)	Claims 1-30	YES
	Claims NONE	NO

2. Citations and explanations:

Please See Continuation Sheet

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/43253

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 8 and 29 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 8 and 29 are indefinite for the following reason(s): Claims 8 and 29 fail to describe with clarity the adherent antimicrobial barrier composition, comprising: heat as the antimicrobial agent, a gelling or thickening agent, an emulsifier or stabilizer, and a surfactant.

Claims 11-21 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 11-21 are indefinite for the following reason(s): In Claim 11, lines 4-7, Applicant should amend the claim language as follows: "an adherent sacrificial composition, wherein the sacrificial composition is partially transferable between the cutting implement and the target surface during cutting, whereby a protective layer is provide to the cutting implement surface while cutting through the target surface" because the Examiner understands that it is the "adherent sacrificial composition" that is coating the cutting implement and/or the target surface and which is partially transferable between the cutting implement and the target surface during cutting, not the "adherent sacrificial composition layer".

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:
Claims 1-7, 9-10, 22-28, and 30 lack novelty under PCT Article 33(2) as being anticipated by Beerse et. al. [U.S. Patent No. 6,294,186]. Beerse et. al. teach a method [and the antimicrobial barrier composition of claims 22-28 and 30] of reducing or preventing transfer of contamination from a contaminated surface; comprising coating a contaminated surface or portion thereof with a adherent antimicrobial barrier composition (See Specification, col. 3, line 66 to col. 4, line 13), comprising: from about 0.1 to about 25% (wt) of a gelling or thickening agent (See Specification, col. 10, lines 39-42); from about 0.1 to about 10% (wt) of an emulsifier or stabilizer (See Specification, col. 15, lines 1-6); from about 0.05 to about 10% (wt) of a surfactant (See Specification, col. 12, lines 9-12); and an antimicrobial agent, whereby transfer of contamination from the surface is reduced or precluded (See Specification, col. 20, lines 35-43). Beerse et. al. further teach the method [and the antimicrobial barrier composition], wherein the adherent antimicrobial barrier composition further comprises 0.1 to about 15% (wt), or about 1 to about 5% (wt), of one or more C_{1-10} alcohol (See Specification, col. 24, lines 40-44). Beerse et. al. further teach the gelling or thickening agents is present in an amount from the group consisting of from about 0.1 to about 4% (wt), from about 5 to about 15% (wt), and about 2.5% (wt) (See Specification, col. 10, lines 39-42), and is selected from the group consisting of pectin, methylated pectin, gelatin, hydrosylated gelatin, agar, cornstarch, cross-linked starch, depolymerized starch, gelling vegetable protein product, sodium alginate, carrageenan, and combinations thereof (See Specification, col. 9, line 55 to col. 10, line 67). Beerse et. al. further teach the emulsifier or stabilizer is present in an amount from the group consisting of from about 0.05 to about 0.5% (wt), from about 1 to about 5% (wt), and about 0.2% (wt) (See Specification, col. 15, lines 1-6), and is selected from the group consisting of calcium lactate, lecithin, glycerol, and combinations thereof (See Specification, col. 10, line 61). Beerse et. al. further teach the surfactant is present in an amount from the group consisting of from about 0.05 to about 0.5% (wt), from about 1 to about 5% (wt), and about 0.2% (wt) (See Specification, col. 12, lines 9-12), and is selected from the group consisting of sodium lauryl sulfate, Tween 20, 40, 60, and 80, and combinations thereof (See Specification, col. 11, lines 50-54). Beerse et. al. further teach the antimicrobial agent is at least one of an acidic agent and a basic agent, present in an amount selected from the group consisting of from about 0.1 to about 15% (wt), from about 1 to about 5% (wt), and about 2% (wt) (See Specification, col. 20, lines 39-43), suitable to impart a pH of less than about 3, or greater than about 10 (See Specification, col. 19, lines 37-41), and is selected from the group consisting of acetic acid, citric acid, and lactic acid, acidified calcium sulfate...glycolic acid...and combinations thereof (See Specification, col. 36, lines 15-35). Beerse et. al. further teach the antimicrobial agent is selected from the group consisting of proteases, lipases and phospholipases, alcohols, and combinations thereof (See Specification, col. 8, lines 29-32). Beerse et. al. further teach the method further comprising, prior to coating, heating the adherent antimicrobial barrier composition to a temperature equal to or great than 80°C (See Specification, Example 3, col. 49, line 6; Examples 36-38, col. 57, lines 13-37). Beerse et. al. further teach the antimicrobial barrier composition is provided as a formulation selected from the group consisting of semi-solids, gels, liquids, syrups, aerolized formulations, foams, colloidal suspensions, and combinations thereof (See Specification, Examples 1-40).

Claims 8 and 29 lack novelty under PCT Article 33(2) as being anticipated by Zimmerman et. al. [U.S. Patent No. 5,846,594]. Zimmerman et. al. teach a method of reducing or preventing transfer of contamination from a contaminated surface, comprising applying heat to a contaminated surface or a portion thereof (See Specification, col. 8, lines 1-11).

Claims 11-21 lack an inventive step under PCT Article 33(3) as being obvious over Beerse et. al. Beerse et. al. teach a

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

method of reducing or precluding transfer of surface contamination (See Specification, col. 3, line 66 to col. 4, line 13 - antimicrobial composition is highly efficacious for household cleaning (e.g. hard surfaces like floors, countertops) and industrial and hospital applications (sterilization of instruments)). Beerse et. al. fails to teach the method of claim 11, wherein the method comprises: coating, prior to cutting through a targeted surface, at least one of: a cutting implement or a portion thereof; and the target surface or a portion thereof with an adherent sacrificial composition, which is partially transferable between the cutting implement and the target surface during cutting, whereby a protective layer is provided to the cutting implement surface while cutting through the target surface. It would have been obvious to coat, prior to cutting through a targeted surface, at least one of a cutting element and the target surface with the adherent sacrificial composition because coating the cutting implement or the target surface prevents the contaminated instrument or target surface from transferring bacteria to the other. The coating serves as a protective layer to the instrument and/or the target surface. Because of the antimicrobial composition's fluid nature, as taught in Beerse et. al., it would have been obvious that a portion of the sacrificial composition would be transferable between the instrument and the target surface during cutting.

Claims 1-30 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.